

### **REMARKS**

The present paper is responsive to the final Office Action mailed on April 30, 2010. By this paper, the Applicants request continued examination of the claims of the application, and reconsideration of the rejections.

Claims 33 and 66 are amended to recite a pH-sensitive mucoadhesive layer, and to recite that that layer consists essentially of the water insoluble swellable anionic mucoadhesive polymer and anionic pH-sensitive film-forming polymer as claimed. No new matter is added. Support for the terms pH-sensitive mucoadhesive layer, water-insoluble swellable mucoadhesive polymer, and pH-sensitive film-forming polymer is as set forth in previous responses. Support for the term anionic is set forth below in item A.

Claim 63 is amended to delete the term "about." No new matter is added.

The Examiner will recognize that new claims 67 and 68 are simply alternative claiming strategies for subject matter presented in claim 33, and that no new matter is added.

#### **A. THE REJECTION OF CLAIMS UNDER 35 U.S.C. §112, 1<sup>ST</sup> PARAGRAPH IS BELIEVED TO BE OVERCOME.**

##### **1. The rejection of claims over the term "anionic."**

The Examiner rejects claims 33-34, 36-46, 51, 57-57[sic], and 62-66 as failing to comply with the written description requirement. Specifically, the Examiner objects to the claim limitations concerning "anionic polymers," and states that for any element to be excluded "it must be either positively or negatively recited in the specification." Respectfully, this is not an accurate statement of the law on written description, and the Applicants reiterate that support is set forth in the present specification for this limitation.

Again, the case law regarding Section 112, 1<sup>st</sup> paragraph is unequivocal in holding that it is sufficient if the originally filed disclosure would have conveyed to one having ordinary skill in the art that the inventor had possession **of the concept** of what is claimed.<sup>1</sup> Indeed, *In re Anderson* stands for the proposition that even a term appearing nowhere in the specification can be added to a claim without constituting new matter as

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<sup>1</sup> *In re Anderson*, 471 F.2d 1237, 176 USPQ 331(CCPA1973).

long as the concept of what is being claimed is present in the original disclosure. Newly added claim limitations must be supported in the specification through express, implicit, or inherent disclosure.<sup>2</sup> In keeping with the teachings of *In re Anderson* and the MPEP, full support for the disputed limitation is present in the Specification. As will be demonstrated below, in fact the Applicant's disclosure teaches not only the concept, but also actual examples of use of anionic polymers in the present invention, and are entitled to add limitations to the claims to that effect.

The Board of Patent Appeals and Interferences (BPAI) recently issued a ruling in a similar fact pattern wherein an Examiner rejected a claim on written description grounds for lack of express recitation of the limitation.<sup>3</sup> A copy of that opinion is appended hereto as **Exhibit A** for the Examiner's convenience. In that case, a negative limitation relating to amplification of mRNA was inserted to the claims during prosecution, and the Examiner objected on written description grounds. The Board responded as follows (see the opinion beginning at page 15):

“ ‘[A]n examiner can make out a prima facie case of lack of adequate written description, thus shifting the burden of production to the applicant, simply by identifying specific claim limitations and stating that despite reviewing the specification, he could not find support for those limitations.’ *Hyatt v. Doll*, 576 F.3d 1246 (Fed. Cir. 2009). Therefore, the issue in this appeal is whether Appellants rebutted the Examiner's determination that the claims contain subject matter which was not described in the Specification.

#### Principles of law

To satisfy the written description requirement, the inventor ‘must also convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*.’ *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64 (Fed. Cir. 1991). In describing the claimed invention, there is no requirement that the wording be

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<sup>2</sup> Manual of Patent Examining Procedure §§2163, 2173.05(i)

<sup>3</sup> *Ex parte Jennifer Cryer, Peter Kille, Andrew Paul Morby, and Richard Charles Brown*, Appeal 2009-011266 (BPAI, decided April 23, 2010).

identical to that used in the specification as long as there is sufficient disclosure to show one of skill in the art that the inventor ‘invented what is claimed.’ *Union Oil. Co. of California v. Atlantic Richfield Co.*, 208 F.3d 989, 997 (Fed. Cir. 2000). Thus, so long as a person ‘of ordinary skill in the art would have understood the inventor to have been in possession of the claimed invention at the time of filing, even if every nuance of the claims is not explicitly described in the specification, then the adequate written description requirement is met.’ *In re Alton*, 76 F.3d 1168, 1175 (Fed. Cir. 1996).”

The Board went on to discuss specific examples in the Appellants specification showing: 1) that the Appellant had performed its method without mRNA amplification; and 2) reciting alternative methods recognized by the skilled artisan to include amplification of mRNA. The Board held that “[W]hile the phrase “wherein said transcribed mRNA is not amplified prior to the steps .... as recited in claims ... is not literally recited in the Specification, Example 8 describes an example of performing the recited steps in the absence of mRNA amplification. RT-PCR, an amplification method, was recognized as an ‘existing technique’ for analyzing mRNA, but was not utilized in Example 8. In view of these disclosures, persons of ordinary skill in the art would have recognized that amplification could be excluded from the disclosed method. The Specification therefore shows that the inventors ‘invented what is claimed.’ *Union Oil Co. of California v. Atlantic Richfield Co.*, 208 F.3d at 997. The written description rejection is reversed.”

Thus, in the above case the Board found that an express recitation of an example performing the method including the claimed negative limitation, combined with an acknowledgment of the distinction from other methods not so including the negative limitation, fully supported inclusion of the negative limitation in the claims despite lack of an express recitation thereof, without violating the written description requirement.

Such is the case here. The Examiner’s attention is again directed at least to *page 16, ll 19-23*, wherein there is recited “Examples of pH-sensitive film-forming polymers that meet these criteria are, but not limited to, Eudragits® and cellulose acetate phthalate polymers, or derivatives thereof. Eudragits® are synthetic cationic and anionic polymers

of methacrylic acid and methacrylic acid esters in varying ratios” (emphasis added). Thus, support is found in the present specification for both cationic and anionic pH-sensitive film-forming polymers. The fact that the Applicant elects to claim only anionic pH-sensitive film-forming polymers in the present application, and to defer consideration of claiming other described polymers to a subsequent progeny patent application, has no bearing on the analysis under Section 112.

Even more, see the specification at *page 17*, first partial paragraph (especially *ll 15-17*), reciting: “No references or other prior art could be found that describe the use of mucoadhesive gels comprised of anionic polymers ...” Not only did the Applicant expressly consider distinctions between mucoadhesive gels comprising anionic versus cationic polymers at the time of filing, the Applicant specifically noted that mucoadhesive gels comprising anionic polymers had not been found in the prior art for forming films on mucosal surfaces.

Still yet further, specific examples of anionic pH-sensitive film-forming polymers are provided in the specification. See at least *Figure 2*, *Figure 3*, and *Figure 6* showing results from wax-film composites comprising Eudragit S100, and also at least Examples 7 and 8 describing the making of a wax-film composite comprising Eudragit S100, which as shown in the appended **Exhibit B** (see page 1, ¶ 2) is an anionic copolymer. See also at least Examples 1, 2, 5, and 6 describing the making of a pH-sensitive mucoadhesive film-forming gel comprising Eudragit L100, which is likewise an anionic copolymer (see **Exhibit B**). In the present case not only the concept, but also express examples representative of the specific claim limitation (anionic pH-sensitive film-forming polymer), are presented in the specification and the *In re Anderson* standard is clearly met. The Applicant is clearly in possession of the concept of mucoadhesive gels including anionic versus cationic polymers, distinguishes from the prior art based on the concept of use of anionic polymers, and provides specific examples using anionic polymers. Section 112 requires no more of an applicant for patent, and withdrawal of the rejection of the claims as failing the written description requirement for inclusion of claim limitations directed to anionic polymers is respectfully requested.

**2. The rejection of claim 63 for the limitation “from about 2:1 to about 4:1.”**

The Examiner also again rejects claim 63 as failing the written description requirement for the limitation concerning Noveon:Eudragit ratios between about 2:1 to about 4:1, but admits that specific examples of ranges of 2:1, 3:1, and 4:1 are presented. In response, the Applicant amends the claim to recite a limitation of “between 2:1 to 4:1.” The Applicant reiterates that as stated in the MPEP, the “... analysis must take into account which ranges one skilled in the art would consider inherently supported by the discussion in the original disclosure.”<sup>4</sup> In the present case, ranges are expressly disclosed in the Specification which are not so far-reaching as to cause the skilled artisan to question whether the intervening ratios were contemplated. This is not the case where upper, middle, and lower limits are disclosed which represent such a gap as to allow for near-infinite intervening possibilities, whereby claiming the range between the upper and lower ratios violates the written description requirement. That is, the skilled artisan, presented with the specific examples of ratios of 2:1, 3:1, and 4:1 of two compositions, would consider a ratio range of from 2:1 to 4:1 to have been described at least inherently, if not expressly.

In particular, the case of *In re Wertheim*<sup>5</sup> is instructive. In that case, a range of 25%-60% solids was disclosed in a method for freeze-drying coffee. Specific examples of 35% and 60% solids were disclosed in the specification. The Board found that a claim limitation to “at least 35%” solids was not supported as including percent solids outside of any disclosure of the specification.<sup>6</sup> On the other hand, the court held that the person of skill in the art would consider claimed the solids content range of “between 35% and 60%” to be part of the appellant’s invention.<sup>7</sup> The lack of literal support in the appellant’s disclosures did not contradict this finding. The court found that “[T]he PTO has done nothing more than to argue lack of literal support, which is not enough. If lack of literal support alone were enough to support a rejection under §112, then the statement of *In re Lukach*, supra, 58 CCPA at 1235, 442 F.2d at 969, 169 USPQ at 796, that ‘the

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<sup>4</sup> MPEP §2163.05, at pg. 2100-190.

<sup>5</sup> 541 F.2d 257, 191 USPQ 90 (CCPA 1976).

<sup>6</sup> *Id.* at 97.

<sup>7</sup> *Id.* at 98

invention claimed does not have to be describe in *ipsis verbis* in order to satisfy the description requirement of §112 is empty verbiage. The burden of showing that the claimed invention is not described in the specification rests on the PTO in the first instance, and it is up to the PTO to give reasons why a description not in *ipsis verbis* is insufficient.”<sup>8</sup>

It is believed that Section 112 does not require the Applicant to provide specific examples of the fractional increments between the presently discussed ratios, since the upper, lower, and middle ratios are expressly disclosed. The Office has not met its burden of providing reasons why a description not in *ipsis verbis* is insufficient, and therefore this portion of the rejection is believed to have been rebutted. The rejection should be withdrawn.

Summarizing, it is believed that the foregoing arguments and citations of law overcome the Section 112 rejection of claims. Reconsideration is respectfully requested.

**B. THE REJECTION OF CLAIMS 33-34, 36-37, 42-46, 56-57, AND 65 UNDER 35 U.S.C. §103(A) OVER SLAVTCHEFF AND SUZUKI IS BELIEVED TO BE OVERCOME.**

The Examiner takes the position that the above claims are obvious over the teachings of Slavtcheff in view of Suzuki. It is believed that the foregoing amendments and the arguments that follow rebut this rejection.

Slavtcheff teaches adhesive cosmetic strips (see *Abstract*) including a flexible water soluble substrate, an adhesive composition deposited onto the substrate, a liquid crystal thermochromic substance, and an agent interactive with water to ensure a specified temperature rise. Nowhere does Slavtcheff expressly teach or hint at use of a *mucoadhesive* layer, much less the synthetic anionic mucoadhesive polymer expressly claimed herein. Rather, Slavtcheff exclusively contemplates adhesives for securing its color-changing cosmetic strip (see *Col. 1, ll 61-63*) to skin surfaces (*Col. 3, ll 1-4*). This is needed for a primary function of the dermal strip of Slavtcheff, that is, for the adhesive to dry over the area of treatment whereby keratotic plugs adhere to it (*Col. 5, ll 18-24*). There is no indication in Slavtcheff of any need for a mucoadhesive polymer, which is to

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<sup>8</sup> *Id.*

be expected since Slavtcheff does not contemplate use of its cosmetic dermal strip on mucosal surfaces but rather solely on skin.

Not only does Slavtcheff lack any hint of a mucoadhesive layer, Slavtcheff provides no teaching, nor is there any indication that Slavtcheff at all contemplates, a synthetic *pH-sensitive* anionic mucoadhesive layer for delivery of a molecule of interest to mucosa as a function of pH as is expressly claimed herein. Rather, Slavtcheff expressly recites only a *temperature-sensitive* adhesive layer comprising liquid crystal thermochromic substances (*Col. 2, ll 25-65*) wherein a water-interactive agent induces a temperature change of at least 2 ° C (*Col. 2, ll 15-17*) which causes the thermochromic substances to change color to provide a visual indicator to the consumer that the dermal strip has been in place for a sufficient period of time. There is simply no indication in Slavtcheff of any need for a pH-sensitive anionic mucoadhesive polymer for delivery of a molecule of interest. This is to be expected since the Slavtcheff strip is only intended for removing keratotic plugs from dermal surfaces rather than for delivering molecules to mucosal areas.

The Examiner states in the most recent Action that “[T]he pH sensitive mucoadhesive layer is defined within the claim by what it comprises, a water-insoluble swellable anionic mucoadhesive polymer and at least one anionic pH-sensitive film-forming polymer.” It is the Examiner’s position (see page 4) that Slavtcheff discloses such an adhesive composition that “could be selected from anionic film forming polymers.” Respectfully, this is not the test for obviousness even in the post-KSR era. Specifically, it remains a requirement that the skilled artisan be provided some reason for arriving at each and every claim limitation, and further it remains a requirement that the skilled artisan be provided some reasonable expectation of success of combining the prior art teachings to arrive at each and every claim limitations.

The Examiner’s finding appears to be based on the Slavtcheff recitation of various ingredients, including monomers such as methacrylic acid (*Col. 4, ll 51-54*), Carbomer® (*Col. 5, ll 15-17*), and others (see *Col. 5* and *Col. 6*), for use in its dermal adhesives, rather than any reason provided by Slavtcheff or the knowledge in the art to consider the pH-sensitive mucoadhesive polymers of the present disclosure. In a prior Action (the Action mailed on 10-9-2009, at page 5) the Examiner characterized arriving at the

invention of the present disclosure as no more than “ordinary and routine optimization” based on the extensive list of ingredients provided by Slavtcheff. Surely, however, the Examiner can concede that in the chemical arts, mixing of even the same ingredients, in different proportions and/or under different conditions, can lead to compositions having very different and unexpected properties.

In this regard, the Examiner points to no element of Slavtcheff teaching or even hinting at an adhesive having mucoadhesive properties as expressly claimed herein, and certainly Slavtcheff provides no teaching or reason to consider a *pH-sensitive* anionic mucoadhesive polymer for delivering a molecule to mucosa. Rather, Slavtcheff is exclusively directed to an adhesive for adhering to skin, not mucosa, for the recited purpose of removing keratotic plugs. Thus, absent undue experimentation or use of the present Applicant’s specification as a blueprint, each of which is improper, no guidance (or articulated reason) is given to the skilled artisan to arrive at or even consider using any of the Slavtcheff ingredients (with or without inclusion of the teachings of Suzuki) to formulate the presently claimed combination of at least one water-insoluble swellable anionic mucoadhesive polymer and at least one anionic pH-sensitive mucoadhesive polymer for delivering a molecule of interest. As such, Slavtcheff, for lack of any teaching or articulated reason for considering this claim limitation, fails to establish the *prima facie* case for obviousness.

The Examiner cites Suzuki solely for teachings of thin layers for adhesive patches and for use of a wax backing layer. Even taking this as true, the defect in Slavtcheff as a Section 103 reference is not cured. Like Slavtcheff, Suzuki lacks any teaching or reason to consider the anionic polymers recited in the present claims to provide a pH-sensitive mucoadhesive layer for delivering a molecule of interest to a mucosal area, and the *prima facie* case for obviousness is not supported.

On pages 4-5 of the most recent Action, the Examiner states that it is not understood why the Suzuki teaching away was discussed in the previous response, as it was cited only for the proposition of a wax backing layer. For the record, the prior discussion was to moot any future obviousness rejection based on Suzuki as a primary reference. For that reason, the Applicant states again that Suzuki simply does not teach or otherwise contemplate a pH-sensitive mucoadhesive layer as is expressly claimed



herein, comprising at least one anionic pH-sensitive film-forming polymer, and for delivering a molecule of interest to a mucosal area. Rather, Suzuki teaches only a covering material *consisting essentially* of a cellulose lower alkyl ether and a polyacrylic acid or pharmaceutically acceptable salt thereof (emphasis added, see *Abstract*). Thus, in its recitation of “consisting essentially of a cellulose lower alkyl ether and a polyacrylic acid,” Suzuki expressly excludes consideration of the presently claimed pH-sensitive mucoadhesive polymer and of the anionic pH-sensitive film-forming polymer.<sup>9</sup>

In rejecting claims under Section 103 it is the Examiner’s initial burden to present a *prima facie* case for obviousness.<sup>10</sup> Further, to reject a claim as *prima facie* obvious based on features disclosed in one or more references, there must be some suggestion, either in the art itself or in the knowledge available to the skilled artisan, of the desirability of making the combination<sup>11</sup> (“The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination.”) (Emphasis in original). Still further, it is required that a reasonable expectation of success support the finding of obviousness.<sup>12</sup>

Thus, the *prima facie* case of obviousness is established only when the teachings from the prior art, the knowledge available to the skilled artisan, or a combination thereof would appear to have suggested the claimed subject matter to a person of ordinary skill in the art.<sup>13</sup> Also, despite any recent revisions to the MPEP, it remains a requirement to a finding of obviousness that the prior art reference or references must teach or suggest all the claim limitations.<sup>14</sup> This test for *prima facie* obviousness is consistent with the legal principles set forth in *KSR Int’l Co. v. Teleflex Inc.*<sup>15</sup> Summarizing the Supreme Court’s holding in that case, the Federal Circuit Court of Appeals noted that “... the Court acknowledged the importance of identifying ‘a *reason* that would have prompted a

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<sup>9</sup> See, MPEP §2111.03, noting that the transitional phrase “consisting essentially of” is interpreted to be limiting to those materials or steps that do not materially affect the basic and novel characteristics of the claimed invention.

<sup>10</sup> *In re Rijckaert*, 9 F.3d 1531, 1532, 28 USPQ2d 1955, 1956 (Fed. Cir. 1993).

<sup>11</sup> Manual of Patent Examining Procedure ch. 2100, Section 2143.01, p. 131.

<sup>12</sup> *Hodosh v. Block Drug Co., Inc.*, 786 F.2d 1136, 1143 n.5, 229 USPQ 182, 187 n.5 (Fed. Cir. 1986).

<sup>13</sup> *In re Bell*, 991 F.2d 781, 783, 26 USPQ2d 1529, 1531 (Fed. Cir.1993).

<sup>14</sup> Manual of Patent Examining Procedure §2143.

<sup>15</sup> *KSR Int’l Co. v. Teleflex, Inc.*, 127 S.Ct. 1727 (2007), 82 USPQ2d 1385 (2007).

person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does' in an obviousness determination."<sup>16</sup> When determining whether a claim is obvious, an Examiner must make "a searching comparison of the claimed invention - *including all its limitations* - with the teaching of the prior art."<sup>17</sup> Moreover, "there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness."<sup>18</sup>

Admittedly, under the lessened obviousness standard of *KSR v. Teleflex*,<sup>19</sup> an "obvious to try" rationale, that is, combining selected elements from one or more prior art references, can support a rejection under 35 U.S.C. §103 under certain circumstances.<sup>20</sup> However, even under *KSR* and post-*KSR* case law, this only applies when there are a "finite number of identified, *predictable* solutions, with a *reasonable expectation of success*"<sup>21</sup> (emphasis added), and the *KSR* requirement for providing an objective reason leading the skilled artisan to combine references remains. That is, the reasonable expectation of success requirement remains, even when the particular facts permit an "obvious to try" analysis for legal obviousness. This is particularly true in view of recent case law issued from the U.S. Court of Appeals for the Federal Circuit (CAFC). With reference to the decision in *Ortho-McNeil Pharmaceutical v. Mylan*,<sup>22</sup> the CAFC specifically noted that "... the passage in *KSR* posits a situation with a finite, and in the context of the art, small or easily traversed, number of options that would convince an ordinarily skilled artisan of obviousness."

In the present case, the skilled artisan is not faced with a "finite number of identified, *predictable* solutions, with a *reasonable expectation of success*" of a pH-

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<sup>16</sup> *Takeda Chemical Industries Ltd. v. Alphapharm Pty.*, 83 USPQ2d 1169 (Fed. Cir. 2007) (quoting *KSR*, 127 S. Ct. at 1731).

<sup>17</sup> *In re Ochiai*, 71 F.3d 1565, 1572 (Fed. Cir. 1995).

<sup>18</sup> *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1741 (2007) (quoting *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006)).

<sup>19</sup> *KSR International Co. v. Teleflex Inc.*, 127 S.Ct. 1727 (2007), 82 USPQ2d 1385 (2007).

<sup>20</sup> See, Examination Guidelines for Determining Obviousness Under 35 U.S.C. 103 in View of the Supreme Court Decision in *KSR International Co. v. Teleflex Inc.*, Fed. Reg. 72, No. 195, 57526-57535, at pg. 57529.

<sup>21</sup> *Id.* at pg. 57529.

<sup>22</sup> *Ortho-McNeil Pharmaceutical, Inc. v. Mylan Laboratories, Inc. and Mylan Pharmaceuticals, Inc.*, 2007-1223 (Fed. Cir. 2008); see also *Takeda Chemical Industries Ltd. v. Alphapharm Pty.*, 83 USPQ2d 1169 (Fed. Cir. 2007).

sensitive mucoadhesive layer, leading to a *prima facie* case of obviousness. Rather, the skilled artisan is provided only a lengthy list of ingredients, with no reason articulated for the skilled artisan to consider any particular combination thereof to arrive at the presently claimed subject matter other than the guidance provided by the present specification. As discussed above, Slavtcheff fails to teach or provide the skilled artisan an articulated reason to consider a pH-sensitive mucoadhesive layer including at least one water-insoluble swellable anionic mucoadhesive polymer and at least one anionic pH-sensitive film forming polymer as expressly claimed herein. The Suzuki teaching of a wax backing layer does not correct this deficiency. Therefore, neither Slavtcheff, Suzuki, nor any reasonable combination thereof teach or suggest each and every limitation of the present independent claims, nor is any reason articulated that would lead the skilled artisan to use the references independently or in combination to arrive at the presently claimed subject matter. The *prima facie* case of obviousness is not properly supported as to the independent claims, and the rejection must fall. Likewise, the claims depending from claim 33 are in condition for allowance without consideration of obviousness.<sup>23</sup> Reconsideration of the rejection over Slavtcheff and Suzuki is respectfully requested.

**C. THE REJECTION OF CLAIMS 33-34, 36-46, 51, 56, 57, 63 AND 64-66 UNDER 35 U.S.C. §103(A) IS BELIEVED TO BE OVERCOME.**

The Examiner takes the position that the above claims are obvious over the teachings of Slavtcheff in view of Suzuki, further in view of Mantelle. Slavtcheff and Suzuki are presumably cited for the propositions addressed above (see also the Office Action mailed on 10-9-2009, beginning at page 6). Mantelle is cited for a teaching of “use of Noveon® and Eudragit® polymers in adhesive compositions for personal use.”

It is believed that the foregoing amendments and the discussion above of the failure of Slavtcheff/Suzuki to support a *prima facie* case for obviousness likewise rebuts this rejection, the citation to Mantelle for the known trade names/trademarks Noveon® and Eudragit® notwithstanding. For the reasons set forth above, Slavtcheff as a primary

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<sup>23</sup> *In re Fritch*, 972 F.2d 1260, 1266 (Fed. Cir. 1992) (“[D]ependent claims are nonobvious if the independent claims from which they depend are nonobvious”); *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988).

reference fails to teach or articulate a reason for the skilled artisan to include a pH-sensitive mucoadhesive layer as expressly claimed herein for delivery of a molecule of interest to a mucosal surface. Suzuki's teaching of a wax backing does not cure this failure. Likewise, Mantelle's recitation of the known product line of Noveon® and Eudragit® polymers does not adequately support the *prima facie* case for obviousness.

Stated differently, the lengthy teaching of ingredients set forth at least in Slavtcheff and Mantelle does not, without more, provide a basis for an obviousness rejection despite any recent revisions to the Manual of Patent Examining Procedure. Rather, some articulated reason for combining those teachings with a reasonable expectation of success, independent of the mere recitation of ingredients and the blueprint provided by the present Applicant's specification, is necessary. The trade names Noveon® and Eudragit® are applied to a range of different polymers having a range of properties, and thus Mantelle's (and the Examiner's) mere recitation of the trade names does not and cannot rise to the level of a teaching or articulated reason sufficient to provide the skilled artisan a reason to consider combining the teachings of Slavtcheff, Suzuki, and Mantelle to arrive at a pH-sensitive mucoadhesive layer as claimed herein. Reconsideration is requested.

Even more, Mantelle expressly leads the skilled artisan towards a combination of PVP and another bioadhesive (*Col. 4, ll 65 et seq.*: "... the inventors believe that the combination of PVP and another bioadhesive provides for a superior adhesion not attainable by either the PVP or another bioadhesive alone."), unlike the present disclosure and claims. As set forth in a previous response, PVP is a neutral polymer. Thus, Mantelle would not motivate the skilled artisan to consider adhesive polymers without PVP. In contrast, the present amended claims 33 and 66 require that the claimed anionic pH-sensitive mucoadhesive polymer consist essentially of at least one water soluble swellable anionic mucoadhesive polymer and at least one anionic pH-sensitive film-forming polymer, thereby excluding non-anionic polymers. Stated differently, Mantelle provides no reason leading the skilled artisan to arrive at the present combination as claimed, the recitation of Noveon® and Eudragit® notwithstanding.

No combination of Slavtcheff, Suzuki, or Mantelle teaches each and every limitation of the present independent claims. Likewise, no teaching of the references,

express or inherent, provides any articulated reason leading the skilled artisan to combine the references to achieve the presently claimed combination, and the independent claims are believed to be in condition for allowance under the propositions set forth by *In re Ochiaie* and *KSR Int'l*. The dependent claims are likewise believed to be allowable without consideration of obviousness under the proposition set forth in *In re Fritch* and *In re Fine*. Reconsideration of the rejection, and allowance of the claims, is respectfully requested.

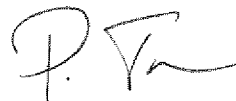
#### D. CONCLUSION

All pending issues and all rejections of record are believed to have been overcome. Therefore, issuance of a prompt Notice of Allowance for the pending claims of the present application is believed to be merited and is respectfully requested. Also, in the Office Action mailed on 02/02/2004, the Examiner required restriction to a number of species relating to the claim limitation of "at least one molecule of interest." In that Action, the Examiner stated that "a claim for 'a wax-film composite' is generic" to those species. Since it is believed that the generic claim (claim 33) to the wax film composite is now in condition for allowance, rejoinder and allowance of claims 48-50 and 53-55 depending therefrom and incorporating each of its limitations is also respectfully requested.

This paper is filed concurrently with a Request for Continued Examination. The Commissioner is authorized to deduct the required RCE fee, and any other fees which may be due, from the undersigned representative's **Deposit Account No. 11-0978**.

Respectfully submitted,

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